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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,357	03/25/2004	John E. Uschold	12013/50601	5454
23838 7590 05/29/2009 KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005				
EXAMINER DESANTO, MATTHEW F				
ART UNIT		PAPER NUMBER		
3763				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/808,357

Applicant(s)

USCHOLD, JOHN E.

Examiner

MATTHEW F. DESANTO

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 13, 15-18, 20-23, 32-36 and 39-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 13, 15-18, 20-23, 32-36 and 39-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "center of the concavity of the first surface is in contact with the second surface" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 47, and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claims 47 and 48 are indefinite because the new limitations would contradict the scope of the claim of the independent claims, since the opening wouldn't be a U-shaped opening anymore.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34, are rejected under 35 U.S.C. 102(b) as being anticipated by Ayres (USPN 3, 906, 932).

Ayres discloses a needle (40) comprising a shaft (10a) having a distal end defining a distal opening and having a longitudinal axis extending through the distal opening, the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end of the shaft, wherein the distal most end is a curvilinear distal tip, wherein the distal end comprises opposing first (16) and second surfaces (18a) and the first surface is indented or tapered towards the second surface; wherein the distal end comprises opposing first and second extensions, which are angled towards each other and the second extension is longer than the first in a direction parallel to the longitudinal axis of the shaft and

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these extensions and mutually define at least one opening offset from the longitudinal axis of the shaft (see figure 2 and entire reference).

Claims 1, 2, 5, 13, 15 - 18, 20, 22, 23, 36, 41, 45, 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Larson (USPN 4,020,837).

Larson a needle comprising a shaft (16) having a distal end defining a distal opening (22) and having a longitudinal axis extending through the distal opening, the distal opening having a projected area (22+20) that is smaller than a cross-sectional area of a section (16) of the shaft proximal to the distal end of the shaft, wherein the distal most end is a curvilinear blunt (30) distal tip (see figure 4, 5 and entire reference) and wherein the distal end has a concavity (18) on the first surface.

Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Ferguson (USPN 2,560,162).

Ferguson a needle comprising a shaft (5) having a distal end defining a distal opening (13) and having a longitudinal axis extending through the distal opening, the distal opening having a projected area (13) that is smaller than a cross-sectional area of a section (5) of the shaft proximal to the distal end of the shaft, wherein the distal most end is a curvilinear distal tip (see figure 1-5 and entire reference) and wherein the distal end has a concavity (15) on the first surface.

Claim 34, 35, 47, 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Magasi (USPN 4826492).

Magasi discloses a closed U-shaped opening (figure 2), as well as a needle comprising a shaft having a distal end defining a distal opening and having a longitudinal axis extending

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through the distal opening, the distal opening having a projected area that is smaller than a cross-sectional area of a section of the shaft proximal to the distal end of the shaft.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ayres (USPN 3, 906, 932) in Jansen et al. (USPN 6,626,864).

Ayres discloses the claimed invention except for the distal tip being blunt.

Jansen et al. discloses the level of skill in the medical art and the variation of the term needle (Column 1, lines 15-32).

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Ayres with the teachings of Jansen et al. because Jansen et al. shows the level of skill in the medical/needle art, and the various types of

needles that are used in medical devices. Thus providing the evidence that it would be obvious to try to modify the sharp needle of Ayres to a blunt needle since this modification would only take routine skill in the art.

Claims 3, 5, 39, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayres with Jansen et al. and further in view of Alchas (USPN 4,537,593).

Ayres and Jansen et al. discloses the device as described above but fails to explicitly disclose a port or that the distal end of the needle is tapered.

Alchas ('593) describes that the distal end of the shaft 26 comprises at least one port (36) on it's side, the distal end terminates in a curvilinear distal tip (31) and the distal end of the shaft (26) is tapered, and the needle (20) being on the distal end of a syringe (117) see figures 1, 2 and 14.

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Ayres with Jansen et al. by incorporating the port and tapered shaft of the type taught by Alchas, in order to vent air and allow access to narrow target areas.

Claims 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larson and further in view of Alchas (USPN 4,537,593).

Larson discloses the device as described above but fails to explicitly disclose a port or that the distal end of the needle is tapered.

Alchas ('593) describes that the distal end of the shaft 26 comprises at least one port (36) on it's side, the distal end terminates in a curvilinear distal tip (31) and the distal end of the shaft

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(26) is tapered, and the needle (20) being on the distal end of a syringe (117) see figures 1, 2 and 14.

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Larson by incorporating the port and tapered shaft of the type taught by Alchas, in order to vent air and allow access to narrow target areas.

Response to Arguments

The examiner has withdrawn the previous 112 Rejection due to the amendment made to the claims.

The examiner feels that the amendment to the claim 32, 34 and 35 fails to explicitly teach viewing the needle from the front end the distal end, and suggests changing the language to read as "when viewed along the longitudinal axis from the front of the distal end". Therefore the examiner still interprets viewing the needle from the side of the needle at the distal end along the longitudinal axis.

With regards to Larson and the interpretation of the last limitation in claim 1, the examiner disagrees with the applicant's interpretation because the distal opening has a tapered section and the area of the tapered section would be less then the area of the lumen at the proximal end. The examiner would also like to note that the claim states a cross section of a section of the shaft proximal to the distal end, and never recites the length of the section that is going to be used to determine the area, thus depending on the dimensions of the section would change the area of the proximal section. Therefore the examiner interprets the area of the proximal section to be greater then the distal opening projected area. The examiner suggests describing that the first surface

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covering a majority of the distal opening, which leads to the smaller projected area. With regards to the method claims, Larson states the needle can be used with a syringe that takes the medicine from the vial and thus treating the patient.

With regards to Ferguson, the examiner disagrees with the interpretation of given, because the depression is formed by a pressure tool, which would press on the rear section and depress the section down, well making the portions connected to the sides maintain their position, thus giving them a higher section (Column 2, lines 20-30).

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Matthew DeSanto

/Matthew F DeSanto/
Primary Examiner, Art Unit 3763